Anesthesiology and Pain Medicine
Volume 14 · Issue 6 · e153566

OPEN PEER REVIEW

Effectiveness of Chamomile in Reducing the Incidence and Severity of Nausea and Vomiting After Middle Ear Surgery: A Triple-Blind Randomized Study

Maryam Sarkhosh, Ehsan Rajabi Visroodi, Hamidreza Samaee, Motahareh Farhadi, Parisa Moradimajd

SUBMITTED	REVISED	ACCEPTED	DOI
17 Aug 2024	7 Dec 2024	13 Dec 2024	10.5812/aapm-153566

About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

More about open peer review: brieflands.com/knowledgebase/opr

Contents

1 **Original submission** Referee 1, Referee 2, Associate Editor, Editor-in-Chief 2
2 **Revision 1** Referee 2, Referee 1, Associate Editor, Editor-in-Chief 4
Authors' reply to reviewers 5
Reviewer and editor comments 9
3 **Revision 2** Referee 1, Associate Editor, Editor-in-Chief 10
Authors' reply to reviewers 11
Reviewer and editor comments 12
4 **Revision 3** Referee 1, Associate Editor, Editor-in-Chief 13
Authors' reply to reviewers 14
Reviewer and editor comments 15

1 Original submission

4 comments · 4 Oct 2024 – 11 Oct 2024

Referee 1 Reviewer

MAJOR REVISION 4 Oct 2024

Dear Author
Thanks for doing this work. I reviewed it and suggest some points for improving it as follows:
1-In the abstract: The times for recording nausea do not match the times in the results section.
2-How did you determine the sample size? (with a reference)
3-What are the primary and secondary aims of the research?
4-It is better to briefly explain the physiopathology of nausea in middle ear surgery and the mechanism of action of chamomile.
5-What drugs were used for the induction and maintenance of anesthesia, and what was the volume of serum intake?
6-What is your plan for nausea and vomiting in the recovery room?
7-In the results section: At first, the author stated that the incidence of nausea and vomiting in group A was lower than in group B, but in the next sentence stated: “The vomiting incidence in group B lower than in group A.” Please correct it.
8-In the table section: The demographic table is replaced with table 2. In the demographic table, the numbers of men and women in the groups must be included. Gender is a factor affecting the incidence of nausea.
9-The reference section: References No. 1, 14, 24, and 25 are not indexed in PUB MED, ISI, or Scopus. It is better to replace them.

With the best regard

Referee 2 Reviewer

MINOR REVISION 10 Oct 2024

Dear AE,
I was pleased to have the opportunity to review the manuscript entitled ‘Effectiveness of Chamomile on Reducing the Incidence and Severity of Nausea and Vomiting After Middle Ear Surgery: A Triple Blind Randomized ’. The manuscript presents interesting data about the effectiveness of chamomile in reducing the incidence and severity of nausea and vomiting after middle ear surgery.
But there are a few potential areas that might be considered:
- A structured abstract should include specific headings such as "Background," "Objectives," "Methods," "Results," and "Conclusions," along with key statistical values (e.g., confidence intervals, effect sizes). This enhances clarity and provides a more balanced summary of the study.

- Although the manuscript mentions the use of a coin-toss method for randomization, there is insufficient detail about how the random allocation sequence was generated and concealed. For instance, how was the sequence generated, and who was responsible for assigning participants to the groups? Additionally, how was blinding maintained during allocation? These details are critical to ensure that bias was minimized in the randomization process.

- The sample size of 110 participants is reported, but there is no discussion of how this number was arrived at. CONSORT guidelines recommend providing a power calculation or rationale for the chosen sample size. This is important to ensure the study is adequately powered to detect a significant effect.

- We would prefer to write the aim or the title of an article on the first line, and on the second and third lines we must mention the main finding(s). In the rest of this part, any gap, question, or hypothesis should be stated, followed by references to other studies.

Associate Editor

MAJOR REVISION 11 Oct 2024

Dear EIC,
I thank the authors and express my appreciation to the researchers. The manuscript presents valuable research. But some revisions are needed. The authors should revise it based on the reviewers' comments. Moreover, the histopathology of nausea in middle ear surgery and the mechanism of action of chamomile must be added to the Background section.

Also, minor changes should be made in the abstract:
- The study design should be mentioned in the first line of the method section of the abstract.

Editor-in-Chief

MAJOR REVISION 11 Oct 2024

Dear Author,
Thank you for submitting the article. It needs some revision. Please revise it based on the reviewers' and AE's comments.

2

Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

1. Reviewer 1

1-In the abstract: Times for the recording of nausea do not match with times in the result section.	Edit in abstract
2-How did you find the sample size? (with a reference)	Sample size and reference of calculate add in study design
3-What are the primary and secondary aims of research?	The primary aim of our study: 1. The aim of this study was to investigate the effectiveness of chamomile in reducing the incidence and severity of nausea and vomiting after middle ear surgery 2. Secondary aims include: Determining the severity of nausea and the amount of vomiting after middle ear surgery following the administration of chamomile capsules and investigating its relationship with the background variables of the patients.
4-It is better to explain shortly about the physiopathology of nausea in middle ear surgery and the mechanism action of chamomile	This paragraph add to introduction: Middle ear surgery is associated with a high risk of postoperative nausea and vomiting due to stimulation of the vestibular labyrinth innervated by the vestibular part of cranial nerve VIII (vistibulocochlear), which in turn activates the CTZ in the area postrema. Indeed, manipulation of the CTZ leads to the activation of the paracellular plexus formation, which is considered the emesis center and ultimately leads to vomiting. In addition, parasympathetic nerve stimulation of the external ear, tympanic membrane,

	middle ear, and inner ear is supplied by cranial nerves V (trigeminal), VII (facial), VIII (vestibular), IV (glossopharyngeal), and X. , will lead to PONV
5-What were the induction and maintenance drugs of anesthesia and the volume of serum intake?	In this study, the approximate duration of anesthesia, the judges used in anesthesia, and the type of anesthesia technique used were the same for all participants, and drugs such as morphine were avoided due to the possibility of nausea and vomiting. In order to induce anesthesia, the following drugs were used: midazolam 2 mg, fentanyl 2µg/kg, thiopental 5 mg/kg, atracurium 0.5 mg/kg. Propofol drip was used to maintain anesthesia.
6-What is your plan for nausea and vomiting in the recovery room?	If the studied patients had more than two episodes of vomiting, ondansetron 2 mg IV PRN was used for them.
7-In the result section: At first, the author said the incidence of nausea and vomiting in group A is lower than in group B, but in the next sentence told: "The vomiting incidence in group B lower than in group A." Please correct it.	This sentence edit in result
8-In the table section: The demographic table is replaced with table 2. In the demographic table, the number of men and women in groups must be included. Gender is an effective factor incidence of nausea.	demographic table is replaced with table 2 and number of men and women in groups included
9-The reference section: Reference No: 1, 14, 24, and 25 are not indexed in PUB MED, ISI, or Scopus. It is better replace them.	References edit

Reviewer 1

2. 2. Reviewer 2

1.The history of previous PONV is of an important part	Add to data of table 2
2.The method of anesthesia is not clear	Add to method

3.The early hours after emergent are the most precious ones for controlling the PONV and you can not conclude from your study that this herb has superiority	Add to method and conclusion

1. Reviewer 3

A structured abstract should include specific headings such as "Background," "Objectives," "Methods," "Results," and "Conclusions," along with key statistical values (e.g., confidence intervals, effect sizes). This enhances clarity and provides a more balanced summary of the study.	Edit abstract
-Although you mention the use of a coin-toss method for randomization, there is insufficient detail about how the random allocation sequence was generated and concealed. For instance, how was the sequence generated, and who was responsible for assigning participants to the groups? Additionally, how was blinding maintained during allocation? These details are critical to ensure that bias was minimized in the randomization process.	detail about how the random allocation sequence was generated and concealed add to methods After providing explanations and obtaining informed consent, they were selected as available and distributed based on random allocation by tossing a coin (on the back and on the coin) into two intervention and control groups. For blinding according to the three-way blind approach of the study, capsules made with the same shape were placed in two envelopes by the pharmacist. The person who did the sampling, the patient who received the drug and finally the statistical consultant who did the data analysis did not know about the allocation of the samples in the intervention and control groups. The intervention group was marked with the letter A and the control group was marked with the letter B in order to prevent the occurrence of bias in collecting and recording the study results and to be able to generalize the results.
-The sample size of 110 participants is reported, but there is no discussion of how this number was arrived at. CONSORT guidelines recommend providing a power calculation or rationale for the chosen sample size. This is important to ensure the study is adequately powered to detect a significant effect.	sample size formula add to methods
-We would rather to write the aim or the title of an article as the first	Edit discussion

line, and in the second and third lines we must mention the main(s) finding(s) and for the rest of this part, any gap, question, hypothesis should be declared and then allude to other studies.	

2 Revision 1

4 comments · 2 Nov 2024 – 9 Nov 2024

Referee 2 Reviewer

ACCEPT 2 Nov 2024

Dear AE,
I reviewed the manuscript again. The great effort in improving the manuscript is highly appreciated.
The authors have addressed all comments.
Thank you

Referee 1 Reviewer

MINOR REVISION 4 Nov 2024

Dear Author

Thanks for responding to the comments. I reviewed your responses and suggested that you change some points as follows:
1-The mechanism of action of chamomile?
2-The article's primary and secondary aims must be written in the methods section, and everything mentioned in response to the reviewer's questions about secondary aims must actually be part of the same primary aims.
3-What is the meaning of the incidence of vomiting after recovery? Is it at time zero and at the time of entry to the ward? How did you manage it before going to the ward?

With the best regard

Associate Editor

MINOR REVISION 9 Nov 2024

Dear EIC,
Some points still need to be refined as requested by one of the reviewers.

Editor-in-Chief

MINOR REVISION 9 Nov 2024

Dear Author:
The great effort in improving the manuscript is highly appreciated. However, there is some room for further improvement that should be considered.

3

Revision 2

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Comments	Edit
1-The mechanism action of chamomile?	The mechanism action of chamomile add to background
2-The article's primary and secondary aims must be written in the methods section, and everything mentioned in response to the reviewer's questions about secondary aims must actually be part of the same primary mains.	Primary and secondary aims of our study add to method section
3-What is the meaning of the incidence of vomiting after recovery? Is it the time of zero and the time of entrance to the ward? How did you manage it before going to the ward?	This means time of zero that add to full text and tables. The researcher was with the patient since she regained consciousness and was taking samples. If the studied patients had more than two episodes of vomiting *before going to the ward*, ondansetron 2 mg IV PRN was used for them.

3 Revision 2

3 comments · 29 Nov 2024 – 1 Dec 2024

Referee 1 Reviewer

MINOR REVISION 29 Nov 2024

Dear Author
After reviewing the revised article, I find that it needs some changes as follows:
1-You must add primary and secondary aims to the text after patient selection.
2-Could you explain the mechanism of action of chamomile?
3-References No. 24 and 25 must be changed because they are not indexed in PubMed, ISI, or Scopus.

Thanks

Associate Editor

MINOR REVISION 1 Dec 2024

Dear EIC,
I wish to express my appreciation to the authors for their efforts and commend the researchers for their valuable manuscript. Nevertheless, there is a need for revisions, and I encourage the authors to review and address the comments provided in order to enhance the quality of the manuscript.

Editor-in-Chief

MINOR REVISION 1 Dec 2024

Dear Author,
The manuscript still needs some revision. Please revise it based on the reviewers' and AE's comments.

4

Revision 3

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Comments	Edit
1-The mechanism action of chamomile?	The mechanism action of chamomile add to background
2-The article's primary and secondary aims must be written in the methods section, and everything mentioned in response to the reviewer's questions about secondary aims must actually be part of the same primary mains.	Primary and secondary aims of our study add to method section after patient selection
3-reference 24 and 25 change	*reference 24 and 25 changed to pub med and ISI reference:* 24. Rajabalizadeh R, Ghasemzadeh Rahbardar M, Hosseinzadeh H. Medicinal herbs in treating chemotherapy-induced nausea and vomiting: A review. Phytotherapy Research. 2022;36(10):3691-708. 25. Matthews A, Haas DM, O'Mathúna DP, Dowswell T. Interventions for nausea and vomiting in early pregnancy. Cochrane Database of Systematic Reviews. 2015(9).

4 Revision 3

3 comments · 13 Dec 2024 – 13 Dec 2024

Referee 1 Reviewer

ACCEPT 13 Dec 2024

Dear Author

Thank you for considering the reviewer's comments. This article is accepted.

With the best regard

Associate Editor

ACCEPT 13 Dec 2024

Dear EIC,
The great effort in improving the manuscript is highly appreciated.
The authors have addressed all the comments.

Editor-in-Chief

ACCEPT 13 Dec 2024

Dear Authors,
We appreciate your attentiveness and prompt response to the reviewer's feedback. Now, your manuscript is acceptable.